Guidelines for ACUC Oversight of Animal Study Proposal Activities in Shared and Central Facilities

Oversight and monitoring of ongoing animal study proposal activities to ensure compliance with all regulations, policies and procedures is a priority for all NIH Animal Care and Use Committees (ACUC). Of utmost importance in this process is monitoring of animal use and study proposal compliance when animals are housed in shared or central facilities operated by another Institute/Center (IC).

Because management practices supporting animals in shared or central facilities are under the purview of a lead IC and its ACUC, systems to address program monitoring must be established between the lead and user ICs and their ACUCs.

This guideline outlines the processes for the monitoring of animal study proposal activities in shared and central facilities. The final responsibility for the research use of each animal is with the Principal Investigator (PI) and their IC ACUC.

The principal responsibility for monitoring animal care in shared or central facilities lies with the lead IC, user ACUCs are required to monitor the activities of their IC's investigators within shared or central facilities. Two members of the user ACUC shall perform on-site assessments of their animals and associated animal activities in shared or central facilities. Monitoring will be performed through:

- physical visits (at least semiannually), and may include,
- professional interactions, and/or
- review of reports and records
- assessment of IC animals
- procedure spaces used by IC Investigators

Such assessment visits will be coordinated with the facility management and veterinarian of the shared or central facility.

Minor issues related to facility operations, veterinary care or technical support may be handled informally by the user IC's veterinary or management staff. Observations affecting the IC's animals should be shared with facility management and the lead IC ACUC. In the event corrective action(s) taken by the Shared or Central facility management are deemed incomplete or inadequate, the User IC ACUC and the Lead IC ACUC shall then meet and attempt resolution of the remaining disagreement(s).

Issues considered to be "significant deficiencies", i.e. that potentially or actually impact the health or well-being of animals, must be promptly reported to the Director, Office of Animal Care & Use to assist in determining if the issue will be classified as a significant deficiency and if the issue will need to be reported to the Office of Laboratory Animal Welfare (OLAW).

OLAW reportable events will be processed as outlined in PM 3040-2 paragraphs F.13.b.6.-8. "ACUC Responsibilities."

When an investigation results from actions/inactions by the facility staff or as a result of a facility related event, the lead IC ACUC, ORS ACUC, or ORF will assume primary responsibility for the investigation and resolution of the issue.

When an investigation results from actions/inactions by an investigator or their staff, the PI's IC ACUC will assume primary responsibility for the investigation and resolution of the issue.

The investigating ACUC will keep the other impacted ACUCs informed of the outcome of the investigation via direct communications and/or sharing copies of the draft and final summary memos.

In addition to PM 3040-2, ACUCs are encouraged to use the "Checklist for ACUC Incident Investigation" as a resource in conducting and reporting the investigation.

References:

NIH Policy Manual 3040-2: <u>Animal Care and Use in the Intramural Program</u> PHS Policy on Humane Care and Use of Laboratory Animals, 2015

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